Citation:

Hakanen M, Lagström H, Kaitosaari T, Niinikoski H, Näntö-Salonen K, Jokinen E, Sillanmäki L, Viikari J, Rönnemaa T, Simell O. Development of overweight in an atherosclerosis prevention trial starting in early childhood. The STRIP study. *Int J Obes* (Lond). 2006 Apr; 30 (4): 618-626.

PubMed ID: 16446743

Study Design:

Randomized Controlled Trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To examine whether nutrition counseling (primarily reducing saturated fat intake) given to study children and their families would decrease development of overweight and obesity.

Inclusion Criteria:

Infant at routine five-month well-baby visit.

Exclusion Criteria:

Children who had a chronic disease that might have an effect on body weight development.

Description of Study Protocol:

Recruitment

Families were recruited by nurses at the well-baby clinics at the infant's routine five-month visit.

Design

Prospective cohort study.

Dietary Intake/Dietary Assessment Methodology

Food consumption was recorded in food diaries for three to four days before each visit, and the nutrient composition was analyzed with a the Micro-Nutrica computer program.

Intervention

- The intervention group received counseling given by a nutritionist and physician at one- to

three-month intervals until the child was two years old and twice a year thereafter. During the first years, counseling was mainly focused on the child's diet and was given to the parents. From the age of 7.5 years onwards, more information and suggestions were given directly to the child. At the beginning of the trial, nutrition counseling was mainly aimed at reduction of the child's intake of saturated fat. Recommended total fat intake was 30% of energy intake after two years and 30% to 35% of intake between years one and two. Suggestions were made to change from products containing large amounts of saturated fat to products with less saturated fat or more unsaturated fat. Suggestions were also made to increase the amount of physical activity
- The control group received similar basic health education as routinely given at Finnish well-baby clinics and school health care (twice yearly until the child was seven years of age and once yearly thereafter). No suggestions on use of fats were made and dietary issues were discussed only superficially. No suggestions about physical activity were made. Obese children were an exception and were given counseling regarding weight management.

Statistical Analysis

- Enders were analyzed separately
- Fisher's exact tests were used to compare the proportions of overweight and slim children in the intervention and control groups at the age of 10 years
- Potential factors predicting the development of overweight were analyzed with general estimating equations
- Repeated measured ANOVA was used to study the main effects and interactions between the study group and time in height SD and weight for height
- Two-sample T-test were run at each age point to compare the weights for height of the intervention and control girls since an interaction was found between the study group and time factors.

Data Collection Summary:

Timing of Measurements

Height and weight were measured at least once per year.

Dependent Variables

- Weight for height: Percent deviation from the mean values of healthy Finnish children of the same sex:
  - Overweight: More than 20% above the mean
  - Obese: 40% or more above the mean
  - Slim: More than 15% below the mean
- Body mass index (BMI) at 10 years:
  - Overweight: BMI exceeded 19.86kg/m^2 for girls and 19.84kg/m^2 for boys
  - Overweight: BMI exceeded 85 percentile of US CDC's growth charts.

Independent Variables

Intervention or control group.

Description of Actual Data Sample:

- *Initial N:* 1,062
- *Attrition (final N):* 585 at 10 years of age
- *Age:* Seven months through 10 years
- *Location:* Turku, Finland.

Summary of Results:

Key Findings

- After the age of two years, there were continuously fewer overweight girls (weight for height more than 20% above the Finnish mean) in the intervention group compared to the control group. At age 10 years, 10.2% of girls in the intervention group and 18.8% of girls in the control group were overweight (P=0.0439). For 10-year-old boys, 11.6% were overweight in the intervention group compared to 12.1% in the control group (P = approximately 1.00)
- Using international cut off points for BMI (BMI higher than 19.86kg/m^2 for girls and higher than 19.84kg/m^2 for boys), the prevalence of overweight for 10-year-old girls and boys in the control group was 23.6% and 17.8%, respectively
- Using US CDC growth charts (at or above 85th percentile), the prevalence of overweight for 10-year-old boys and girls in the control group was 22.9% and 19.1%, respectively.

Other Findings

- Using international cutoff points for BMI, the prevalence of overweight for 10-year-old girls and boys in the control group was 23.6% and 17.8%, respectively
- Using US CDC growth charts (at or above 85th percentile), the prevalence of overweight for 10-year-old boys and girls in the control group was 22.9% and 19.1%, respectively
- Possible predictors of overweight included child's age (risk of overweight increased by 39% and 41% for girls and boys, respectively each year), mother's BMI (one unit increase in BMI increased risk of overweight by 16% in girls, but was not significant in boys), father's BMI (one unit increase in BMI increased risk of overweight by 10% and 14%, respectively)
- The weights-for-height of boys in the intervention group and the control group were similar (P=0.30)
- Until the age of five years, the girls in the intervention group were somewhat heavier than those in the control group, but thereafter the reverse was true (P=0.0108; but, the difference between the groups was not significant at any single age point)
- Two girls and one boy in the intervention group were classified as obese (40% or more above Finnish mean) at some age point, compared to eight girls and six boys in the control group.

Author Conclusion:

Individualized dietary and lifestyle counseling given twice a year since infancy decreases prevalence of overweight in school-aged girls.

Reviewer Comments:

Study Strengths

- *Long follow-up period (10 years)*

- *Control comparison group was standard of care*
- *Weight and height were measured at least yearly*
- *More than one definition of overweight was used*
- *Several predictors of overweight were considered*
- *No difference was found in the proportions of dropouts among overweight and normal weight children at any age point.*

Study Limitations

- *At 10 years, follow up was 55% (N=585)*
- *Families knew which group they were randomized to, which may have affected the content of food diet reporting.*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions		
1.	**Was the research question clearly stated?**	N/A
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	N/A
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	N/A
1.3.	Were the target population and setting specified?	N/A
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes

2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	???
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	No
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	???
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	No
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	No
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A

5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	N/A
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes

8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	No
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	N/A
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes